



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,466	08/07/2006	Ji Hoon Jeong	2236.0180000/JUK/SMW	4435
26111 7590 07/01/2010 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
PITRAK, JENNIFER S				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
07/01/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/551,466

**Applicant(s)**

JEONG ET AL.

**Examiner**

JENNIFER PITRAK

**Art Unit**

1635

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/9/2010 has been entered and considered.

### ***Remarks***

Claims 1-4 and 6-14 are pending. Claims 9 and 10 have been amended and now fall within the scope of the elected invention. Claims 11-14 are withdrawn. Claims 1-4 and 6-10 are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102 - Withdrawn***

The rejection of claims 1, 3, 4, and 6 under 35 U.S.C. 102(b) as being anticipated by Cook, et al. (U.S. Patent 5,717,083) as evidenced by Agrawal et al., (Proc. Natl. Acad. Sci, 1988, 85, 7079-7083) and [www.newton.dep.anl.gov](http://www.newton.dep.anl.gov) (of record) is withdrawn. The amendments to the claims have obviated the rejection.

***Claim Rejections - 35 USC § 103 - withdrawn***

**Tullis, et al. and Goodchild, et al.**

The rejection of claims 1-4, 6, and 7 under 35 U.S.C. 103(a) as being unpatentable over Tullis (1990, US Patent 4,904,582, of record) and Goodchild (1990, Bioconj. Chem., v.1:165-187, of record) is withdrawn. The amendments to the claims have obviated the rejection.

**Tullis, et al. and Goodchild, et al. in view of Bennett, et al.**

The rejection of claims 1-4, and 6-8 under 35 U.S.C. 103(a) as being unpatentable over Tullis (1990, US Patent 4,904,582, of record) and Goodchild (1990, Bioconj. Chem., v.1:165-187, of record) in view of Bennett, et al. (1994, J. Clin. Invest., v.93:820-828, of record) is withdrawn. The amendments to the claims have obviated the rejection.

**New Rejections Base on Claim Amendments**

***Claim Rejections - 35 USC § 103 - NEW***

**Hoffman, et al.**

Claims 1, 2, 4, 6, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman, et al. (US Patent 7,737,108, filed 01/05/2001).

The claims are directed to a conjugate for gene transfer wherein the conjugate comprises an antisense oligonucleotide and a hydrophilic polymer, such as PEG, wherein the polymer is covalently attached to the end of the oligonucleotide by an acetal bond. Claims 9 and 10 are directed to a product-by-process wherein the product is the same as that claimed in claim 1, an

antisense oligonucleotide-polymer conjugate. The patentability of a product does not depend on its method of production. See MPEP 2113.

Hoffman, et al. teach antisense oligodeoxynucleotides linked to a hydrophilic polymer such as PEG by an acetal bond (column 4, lines 27-34 and lines 46-51). Oligodeoxynucleotides comprise deoxyribonucleosides linked by phosphodiester bonds. Hoffman, et al. exemplify the use of PEG having a molecular weight of 5kD (column 21, lines 66-67). Hoffman, et al. do not specifically teach that the polymer is attached to an end of the oligonucleotide or that the polymer conjugated to the oligonucleotide has a molecular weight of over 500 Daltons.

It would have been obvious to one of skill in the art at the time of the instant invention to make an antisense oligonucleotide conjugated to PEG via an acetal bond because Hoffman, et al. teach such a conjugate. It would have been obvious to attach the PEG to an end of the oligonucleotide because the ends of the oligonucleotide are free (i.e., not attached to another nucleotide). It further would have been obvious to use PEG that has a molecular weight that is greater than 500 Daltons because Hoffman, et al. exemplify the use of PEG having a molecular weight of 5000 Daltons. Therefore, the claims would have been obvious at the time the instant invention was made.

Hoffman, et al. and Tullis, et al.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman, et al. (US Patent 7,737,108, filed 01/05/2001) as applied to claims 1, 2, 4, 6, 7, 9, and 10 above, and further in view of Tullis (1990, US Patent 4,904,582, of record).

Claims 1, 2, 4, 6, 7, 9, and 10 are described above. Claim 8 is to a conjugate for gene transfer comprising a hydrophilic polymer and an antisense oligonucleotide comprising a nucleotide sequence complementary to a portion or entire nucleotide sequence of the c-myc gene.

Hoffman, et al. render claims 1, 2, 4, 6, 7, 9, and 10 obvious for the reasons presented in the preceding rejection. Hoffman, et al. does not teach the antisense oligonucleotide-hydrophilic polymer conjugate wherein the antisense oligonucleotide is complementary to a portion or to the entire nucleotide sequence of the c-myc gene (instant claim 8) or wherein the antisense oligonucleotide has a molecular weight ranging from 1000-50000 daltons (instant claim 3).

Tullis describes oligonucleotide conjugates for transport across cellular membranes for modulating gene expression (abstract). In Table 1 in column 19, Tullis discloses the "MBF 20 antisense C<sub>2</sub>-PEG" probe that comprises a 20-nucleotide phosphodiester-linked molecule conjugated to PEG (M<sub>r</sub> = 3500). Such a probe is complementary to a portion of the c-myc gene. Tullis teaches that the PEG group can be added to 5'- or 3'-end of the antisense oligonucleotide by various protocols (column 5, line 44 to column 6 line 8). According to the website, [www.newton.dep.anl.gov](http://www.newton.dep.anl.gov), a 20-nucleotide single-stranded DNA molecule has a molecular weight of approximately 6600 daltons (330 daltons per nucleotide).

It would have been obvious to one of skill in the art at the time the instant invention was made to make an antisense-PEG conjugate wherein the antisense oligonucleotide comprises a sequence that is complementary to a portion of the c-myc gene and wherein the PEG is conjugated to the oligonucleotide via an acetal bond because Tullis, et al. teaches antisense oligonucleotide-PEG conjugates wherein the oligonucleotide comprises a sequence having

complementarity to a portion of the c-myc gene and Hoffman, et al. teach that antisense oligonucleotides can be conjugated to PEG via an acetal bond.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Pitrak/  
Examiner, Art Unit 1635